



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,855	07/25/2000	Robert Tam	213/102-US4	6566

34284 7590 11/04/2003

ROBERT D. FISH; RUTAN & TUCKER, LLP
P.O. BOX 1950
611 ANTON BLVD., 14TH FLOOR
COSTA MESA, CA 92628-1950

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 11/04/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/624,855

Applicant(s)

TAM, ROBERT

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Response to Arguments

Withdrawal of Finality

Finality of the rejection of the last Office action is withdrawn. An action on the merits of claims 2, 4 and 6 – 10 is set forth below.

35 U.S.C. 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brillanti et al., *Gastroenterology*, Vol. 107, 812-817, 1994.

Claim 2 is drawn to a method of modulating Type 1 and Type 2 responses of lymphocytes contained within an environment by administration of Ribavarin and interferon in a concentration which increases the Type 1 response and suppresses the Type 2 response.

Claim 4 is drawn to a method of treating a patient having a disease which includes a viral component and a non viral component, comprising administration of Ribavarin in a concentration which increases the Type 1 response and suppresses the Type 2 response.

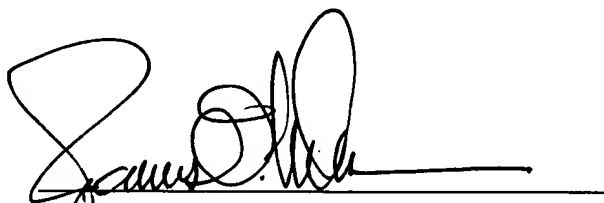
Claims 6-10 are drawn to a method of inhibiting a virus by growing a virus in an environment (hepatocytes or liver) having lymphocytes which produce Type 1 and Type 2 cytokine responses and adding ribavarin to the environment in a concentration for the

Art Unit: 1623

purpose of increasing the Type 1 response and suppressing the Type 2 response, wherein the virus comprises Hepatitis C.

Brillanti teaches the treatment of Hepatitis C, a disease which affects the liver and hepatocytes, via administration of ribavarin. Although Brillanti does not specifically disclose the increase of the Type 1 response and suppression of the Type 2 response, the Type 1 and Type 2 response is seen as merely an affect of the administration of ribavarin and thus an inherent property. Assuming *arguendo* that the language "a disease which contains a viral component and a non-viral component is a limitation, the non-viral component is associated with the manifestation of the virus; thus treatment of the virus, treats the non-viral effects as well. It is noted that claims 2, 4 and 6 contain preamble language which sets forth an intended use, which does not limit the scope of the claim. In claims 2, 4 and 6, the Type 1 and Type 2 responses (and modulation thereof) are effects of the practice of the method. The main body of the claim is the administration of ribavarin or ribavarin and interferon. The prior art may anticipate even if those of ordinary skill in the art did not recognize the inherent characteristic or functioning of the prior art. "Insufficient prior understanding of the inherency properties of a known composition does not defeat a finding of anticipation". *Atlas Powder*, 190 F.3d 1349.

Howard V. Owens
Patent Examiner
Art Unit 1623

A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.